Potential Implications of Genomics for Regulatory and Risk Assessment Applications at EPA

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Advances in genomics will have significant implications for risk assessment practice and regulatory decision making. The Agency's Interim Policy on Genomics (2002) states that, while genomics data may be considered in the decision-making process at this time, these data alone are insufficient as a basis for decisions. Genomics information will be considered for assessment purposes on a case-by-case basis only. Following release of the Interim Policy on Genomics (2002), a Genomics Task Force was formed at the request of EPA's Science Policy Council (SPC). The group was charged with the task of outlining the anticipated applications and implications of genomics for EPA programs and policies.

The Genomics Task Force thus developed a document that describes the implications of the use of genomics technologies in Agency practice. Although understanding genomic responses with respect to adverse ecological and/or human health outcomes is far from established, it is important to begin to consider the likely future impacts of genomics technologies on risk assessment and regulatory decision making. Four areas were identified as those very likely to be influenced by genomics: (1) prioritization of contaminants (chemicals and microbes) and contaminated sites, (2) monitoring, (3) reporting provisions, and (4) risk assessment. The document also outlines ongoing Agency research and research needs for each of these four areas.

Three categories of overarching challenges associated with genomics were identified: research, technical development, and capacity. The research challenges are (1) linking genomics information to adverse outcomes, and (2) interpreting genomics information for risk and hazard assessment. The technical challenge is the development of a framework for analysis and acceptance criteria for genomics information for scientific and regulatory purposes. Two capacity/human capital challenges are (1) applying strategic hiring practices to recruit individuals who possess "genomics core competencies," and (2) training EPA risk assessors and managers to interpret and understand genomics data in the context of a risk assessment. Recommendations for addressing these challenges are made by the Task Force.

The Agency needs to be proactive in identifying, developing, and standardizing applicable genomics approaches. Additionally, many scientific, policy, ethical, and legal concerns will need to be addressed. It is essential for the Agency to continue to collaborate with other federal agencies, academia, the regulated community, and other stakeholders in order to benefit from ongoing advances in genomics in the wider scientific and regulatory communities.